

AWARD NUMBER: W81XWH-14-2-0005

TITLE: Interventions for sustainable weight loss in military families

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RECIPIENT: Tufts University
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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT <p>Through the reporting period, recruitment continued at all study approved military installations in an effort to reach our originally planned target recruitment of 290 adult family members of Active Duty / Retirees (ADMP). To enhance our marketing efforts, we received IRB approval to create a study Facebook Page to share with Facebook groups at our corresponding study military installations in an effort to widen our exposure. Furthermore, through connections made at the 2017 IPR meeting, we participated in discussions with LTC McKnight (Principle Advisor and Military Attaché Environmental Science Engineering Officer Military Operational Medicine Research Program) and Joyce Wessel Raezer (Executive Director, National Military Family Association). To combat the recruitment challenges being faced, the idea of including family members of Military Reservists was discussed, but was later advised/determined to be unfeasible in regards to the time and efforts necessary for the approval process to include this population. Additionally, LTC Bukhari (Director, Nutrition Services Department Walter Reed National Military Medical Center) proposed we include Walter Reed as a site for recruitment and study events for which we began to initiate the approval process however, it was later determined that said process would not coordinate with our study timeline and therefore we did not follow through with the additional study site.</p> <p>We did however continue to utilize our recruitment efforts at our approved study sites and enrolled participants with our: 3rd group from Fort Campbell; 2nd group from Fort Carson, 2nd group from New London Navy Sub Base; 6th group from Fort Drum; and 6th group from Hanscom Air Force Base. With these additional groups our enrollment climbed to 238 adult family member of ADMP's participants. Due to recruitment/enrollment not yielding the numbers we originally expected; we submitted/received approval for a revised statement of work (SOW). Contained in the revised SOW (along with a subsequently revised protocol which was approved) were the procedures to close recruitment and move the primary objective of the study to a 12 month change in weight from the originally intended 24. In doing so, the occurrence of the final blood draw was switched to the 12 month milestone from the 24 in those participants who have not completed 12 months in the study as of January 1st, 2018. These procedures were carried out with participants since the date of approval and all intervention and outcome data collection events have occurred as scheduled. The intervention and outcome data collection is schedule to finish for all participants by December, 2018.</p>		

15. SUBJECT TERMS Military dependents, recruiting, military bases, obesity					
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1. INTRODUCTION:

Obesity and overweight are at epidemic levels in American Warfighters and their family members, and impact health, health care costs, absenteeism and physical performance. This study will test an innovative behavioral intervention in a clinical trial of overweight and obese adult dependents of active duty military personnel (ADMP) and retired ADMP to determine: a) whether the new intervention, called Healthy Weight for Living (HWL), results in more sustainable weight loss and health benefits over 2 years when compared to current best practices (CBP), and b) whether there is a “ripple effect” of program benefits to the obese and overweight ADMP or retirees who live with program participants. Our central hypothesis is that weight management interventions comprised of multiple strategies focused on hunger suppression are particularly effective for sustainable weight loss and benefit not only the immediate recipient but also family members including ADMP or retirees. This hypothesis has been formulated on the basis of strong preliminary data and will be tested in a 2-year randomized trial comparing the HWL intervention to CBP. Outcomes will include change in weight in adult dependents and ADMP as well cardiometabolic risk factors and quality of life. This study is innovative and timely because there is widespread recognition that effective approaches to weight control are urgently needed for American Warfighters and their families. Successful results will constitute a major breakthrough in a field where advances are much needed, and due to the racial, socioeconomic and regional diversity of ADMP will be readily translatable to the general population.

2. KEYWORDS:

- Obesity
- Weight loss
- Military dependents
- Active duty military personnel
- Recruitment
- Military bases
- Behavioral weight loss program

3. ACCOMPLISHMENTS:

- **What were the major goals of the project?**

Year 1 Goals

- Obtain IRB approval to conduct the study and the approval of base commanders to conduct the study at bases (Projected Completion: Year 1; Actual Completion: Year 1)
- Complete Manual of Procedures and study materials for conduct of study (Projected Completion: Year 1; Actual Completion: Year 1)
- Start recruitment of subject population in the study (Projected Completion: Year 1; Actual Completion: Year 1)

- Conduct baseline assessments in recruited population, randomize them to the different interventions and start intervention (Projected Completion: Year 1; Actual Completion: Year 2)
- Start data entry for baseline data (Projected Completion: Year 1; Actual Completion: Year 2)
- Complete all necessary sponsor reports (Projected Completion: Year 1; Actual Completion: Year 1)

Year 2 Goals

- Expand to additional military bases in order to increase our recruiting pool (Projected Completion: Year 2; Completion in Progress)
- Expand study inclusion criteria to include dependents of retired Active Duty Military Personnel (Projected Completion: Year 2, Actual Completion: Year 2)
- Implement the videoconferencing system to deliver the group counseling session to participants while continuing to conduct screening and outcomes testing in-person at the military bases (Projected Completion: Year 2; Actual Completion: Year 2)
- Conduct baseline assessments in recruited population, begin to randomize them to the different interventions and start intervention (Projected Completion: Year 1, Actual Completion: Year 2)
- Start data entry for baseline data (Projected Completion: Year 1; Actual Completion: Year 2)
- Recruit the entire study population, completing baseline assessments, randomizing the entire study population, and starting the intervention: (Projected Completion: Year 3; Completion in Progress)
- Complete all necessary sponsor reports (Projected Completion: Year 2; Actual Completion: Year 2)
-

Year 3 Goals

- Complete recruitment for the entire study population, complete baseline assessments, randomize the entire study population, and start the intervention for the entire targeted population. (Projected Completion: Year 3; Completion in progress, projected for Year 4)
- Receive approval for additional military installations in order to increase recruitment pool in an effort to reach our target enrollment: (Project Completion: Year 3; Actual Completion: Year 3)
- Receive IRB approval to incorporate strategy which we have termed Remote Outcomes in order to accommodate participants who relocate after enrollment in the study: (Projected Completion: Year 3; Actual Completion: Year 3)
- Complete data entry for all scheduled outcome events: (Projected Completion: Completion ongoing, all data has been entered for outcome assessment events that have occurred thus far)

- Complete all necessary sponsor reports (Projected Completion: Year 3; Actual Completion: Year 3)

Year 4 Goals

- Explore new avenues and opportunities in both a broad approach as well as specific to each location in order to increase our recruitment pool (Projected Completion: Year 3; Actual Completion: Year 4)
- Complete recruiting the entire study population (Projected Completion: Year 3; Actual Completion: Year 4)
- Completing baseline assessments and randomizing the entire study population (Projected Completion: Year 3; Actual Completion: Year 4)
- Start the intervention for the entire targeted population. (Projected Completion: Year 3; Actual Completion: Year 4)
- We will continue to offer the IRB approved Remote Outcomes process in order to accommodate participants who are to relocate after initially being enrolled in the study. (Projected Completion: Year 4; Actual Completion: Year 5 *In Progress*)
- Data entry will be completed for all outcome events that occur within the study period. (Projected Completion: Year 4; Actual Completion: Year 5 *In Progress*)

• What was accomplished under these goals?

During this reporting period, we expanded our recruitment efforts by incorporating an HF2 Facebook account as a source to network with, and market through various Facebook groups affiliated with our study approved military installations. Facebook was used in addition to previous strategies such as flyers, banners, and recognition through word-of-mouth. Even with the expanded efforts, we continued to experience minimal inquiries. Due to the slow recruitment, a revised SOW was constructed and the primary outcome of the study was moved to a one year change in weight opposed to the originally intended two.

Although we continued to receive inquiries at a less than expected rate, we were still able to enroll participants for new groups from all our military installations. This brought our total enrollment for adult family members up to 238 participants. With the new enrollees, we completed recruiting the entire study population, ceased recruitment efforts, and closed enrollment. Furthermore, baseline measurements and randomization were completed for the entire study population and all participants have started the intervention.

Subjects continue to complete their participation in the group weight-loss intervention and outcome data collection events as scheduled:

At Hanscom Air Force Base: the first 3 groups enrolled in the study completed the 24 month study milestone. The 4th group of participants completed their 12 month milestone. *The 5th group will complete their 12 month milestone at the end of April, just outside this*

reporting period) We enrolled the 6th group of participants who began the study intervention November, 2017.

At Fort Drum: The first 3 groups of participants completed the 24 month milestone in the study. The 4th and 5th groups completed the 12 month milestone. We enrolled a 6th and final group from Fort Drum, who began the study intervention in November, 2017.

Fort Carson: The first group of participants completed their 12 month milestone in the study. We enrolled a second group of participants, who began the intervention July, 2017.

Fort Campbell: The first and second groups from Fort Campbell completed the 12 month milestone in the study. We enrolled a 3rd group, who began the intervention in July, 2017.

New London Navy Submarine Base: The first group of participants will complete their 12 month milestone event at the end of April. We enrolled a second group of participants, who began the intervention in November, 2017.

Data entry has been completed for all intervention and outcome events mentioned above.

For participants who have relocated during their enrollment in the study and are no longer able to attend in-person outcome data collection events; they have participated in the intervention as normal and we have carried out our remote outcomes procedures in opposition to collecting the measurements in-person at a given study milestone.

All Technical Reports have been completed and submitted for this reporting period.

- **What opportunities for training and professional development has the project provided?**
 - Interventionist, Amy Taetzsch completed training for the Current Best Practice Program
 - Associate Investigator, LTC Asma Bukhari, transitioned to Walter Reed National Military Medical Center as the Chief of Education and Research within the Nutrition Services Department
 - Tufts University has provided the opportunity for various Co-Op positions on the Healthy Families Healthy Forces study team for college students to gain exposure to the clinical research process.
 - Tufts University study team members have completed the Good Clinical Practice in Research course through the Collaborative Institutional Training Initiative

- **How were the results disseminated to communities of interest?**

Nothing to report

- **What do you plan to do during the next reporting period to accomplish the goals?**

During the next reporting period we plan to:

- Complete all outcome data collection events and intervention classes
- Continue the Remote Outcomes Procedures for those participants who have relocated and remain in the study
- Complete all data entry for intervention classes and outcome data collection events
- Complete the cleaning of all data
- Develop Statistical Models and Prepare Manuscripts
- Attend meetings to provide results
- Complete all necessary sponsor reports

4. IMPACT:

- **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report

- **What was the impact on other disciplines?**

Nothing to report

- **What was the impact on technology transfer?**

Nothing to report

- **What was the impact on society beyond science and technology?**

Nothing to report

5. CHANGES/PROBLEMS:

- **Changes in approach and reasons for change**
 - Due to slower than anticipated recruitment, we have amplified our marketing efforts by incorporating an HF2 Study Facebook page in order to expand our recruitment network throughout approved military installations.
 - Due to the high PCS rate, participants now have the option to submit outcome data obtained by their healthcare provider during the time of outcome assessment events after relocating from the military installation where they first enrolled in the study.
 - Due to the lower than anticipated recruitment, we have moved the primary objective of the study to a change in weight over a one year period instead of two.
 - For participants who have not yet completed the one year mark by January, 2018 blood draws will now be completed at the one year milestone instead of two due to the change in primary objective.

- All intervention sessions and outcome data assessments will conclude by December, 2018. For participants who do not reach the 18 month time point in the study prior to December, the 12 month milestone will be their last in the study. Participants, who will reach the 18 to 24 month milestone by December, will be followed up with until that point. Data collected on participants at points which exceed one year, will be analyzed as a separate cohort.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
 - Recruitment being slower than initially expected has caused us to implement the changes in approach necessary to move the primary objective of the study to one year instead of two. These changes are outline above under number 5, “Changes in approach and reasons for change.” Power calculations have been completed to assure that the final population will have the ability for the study to be as successful as feasibly possible at the conclusion of the study.
 - A significant number of participants have experienced or are anticipating a Permanent Change of Station (PCS) making it impractical for them to be present for outcome measurements at the 6 month/12 month/ 24 month in-person events. For these participants, we have offered an option termed Remote Outcomes which will allow participants to utilize their healthcare provider in order to obtain and submit results. Alternatively, participants may also submit their body weight using their scales provided at enrollment and complete the online questionnaires and dietary recalls. These relocated participants may still participate in the group counseling sessions via the videoconferencing system.
- **Changes that had a significant impact on expenditures**
 - Expansion to new locations has occurred in order to increase enrollment and therefore has caused expenses to increase due to travel for screening and outcome events.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
 - There were no significant changes in the use or care of human subjects during this reporting period.

6. PRODUCTS

- **Publications, conference papers, and presentations**
 - **Journal publications.** Nothing to Report
 - **Books or other non-periodical, one-time publications.** Nothing to Report
 - **Other publications, conference papers, and presentations.** Nothing to Report
- **Website(s) or other Internet site(s)**

ClinicalTrials.gov Website: This website contains information about the study to the general public. When results are available, this website will be updated to include the major results from this project.

<https://clinicaltrials.gov/ct2/show/NCT02348853?term=Healthy+Families+Healthy+Forces&rank=1>
- **Technologies or techniques:** Nothing to Report
- **Inventions, patent applications, and/or licenses:** Nothing to Report
- **Other Products**

- We have fully developed the ScienceTrax database for data collection in this study. The database is a sophisticated combination of data entry portals for researchers and also for participants (for those pieces of data that are self-entered). The database also allows for tracking of intervention progress using predefined adherence measures created by the team.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

- **What individuals have worked on the project?**

Name: Roberts, Susan
Project Role: PD/PI
Researcher Identifier:
Nearest person month worked: 2.3
Contribution to project: N/A

Name: Das, Sai Krupa
Project Role: Outcome Chair
Researcher Identifier:
Nearest person month worked: 2.3
Contribution to project: N/A
Funding Support: n/a

Name: Pittas, Anastassios
Project Role: Diabetes Outcomes
Researcher Identifier:
Nearest person month worked: 0.5
Contribution to project: Dr. Pittas provides expertise on diabetes outcomes, analyses, and interpretation
Funding Support: n/a

Name: Saltzman, Edward
Project Role: Study physician
Researcher Identifier:
Nearest person month worked: 0.24
Contribution to project: As of April 8th, 2018; Dr. Edward Saltzman no longer served as the Study Physician.
Funding Support: n/a

Name: Lichtenstein, Alice
Project Role: Cardiovascular Outcomes
Researcher Identifier:
Nearest person month worked: 0.25
Contribution to project: N/A

Name: Gilhooly, Cheryl
Project Role: Co-Investigator
Researcher Identifier:
Nearest person month worked: 1
Contribution to project: N/A
Funding Support: n/a

Name: Martin, Edward
Project Role: Study Coordinator
Researcher Identifier:
Nearest person month worked: 12
Contribution to project: Responsible for operational logistics, tracking of study schedules, outcome assessments, data collection, and data entry for non-electronic forms, and will aid in responses to queries.
Funding Support: n/a

Name: Taetzsch, Amy
Project Role: Interventionist
Researcher Identifier:
Nearest person month worked: 8.5
Contribution to project: As of January 16th, 2018 Amy Taetzsch contribution to the project has been reduced to 0 calendar months.
Funding Support: n/a

Name: Krauss, Amy
Project Role: Interventionist
Researcher Identifier:
Nearest person month worked: 12
Contribution to project: Responsible for delivering the group sessions for the Healthy Weight for Life intervention.
Funding Support: n/a

Name: Rashod Blades
Project Role: Research Assistant
Researcher Identifier:
Nearest person month worked: 12 (November and December 2017)
Contribution to project: Rashod's contribution to the project reflects 12 calendar months for November and December. As of December 31st, 2017; he will no longer be receiving support.
Funding Support: n/a

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
 - N/A
- **What other organizations were involved as partners?**
 - **Organization Name:** US Army Research Institute of Environmental Medicine
 - **Location of Organization:** Natick, MA
 - **Partner's contribution to the project**
 - Facilities and Resources
 - Collaboration

8. SPECIAL REPORTING REQUIREMENTS:

- **QUAD CHARTS:** Enclosed

9. APPENDICES: None

Interventions for sustainable weight loss in military families

ERMS 5793 Log Number 13035001 Yr4 Annual Report
W81XWH-14-2-0005



PI: Susan B. Roberts

Org: Tufts University

Award Amount: \$3,001,102.00

Study/Product Aim(s)

- Obesity and overweight are widespread in military families - effective weight control interventions are urgently needed. The objective of this study is to demonstrate effective, sustainable weight loss program in adult dependents of ADMP, and evaluate anticipated *ripple effect* benefits to ADMP themselves.

Approach

- Conduct a 2-year randomized controlled trial of the two interventions. Outcomes include changes in weight and cardiometabolic risk factors.
- Program recipients are adult dependents of active duty military personnel (ADMP) or retired ADMP. Effects will be evaluated in both program participants and their ADMP, anticipating a ripple effect of benefits to family members.
- Anticipated study outcomes: Sustainable weight loss and improved health in both ADMP and their adult dependents.



Accomplishments: During this reporting period, major activities include; recruiting and enrolling the final groups of participants at each of the approved study locations. In order to accomplish the aforementioned, an HF2 Facebook page was approved and utilized to reach a wider network of potential participants. The intervention has begun for the entire targeted population All baseline data and randomization has been collected / completed. All intervention and outcome data collection events have occurred and been completed as scheduled.

Timeline and Cost

Activities	CY	1	2	3	4	5
Recruitment, baseline testing and randomization						
2 year intervention with outcomes in intervention participants and their ADMP						
Complete data entry and data cleaning, lab and statistical analyses, publication of results						
Estimated Budget (\$K)		\$601	\$756	\$750	\$487	\$406

Goals/Milestones

Objective 1 –

- ✓ Obtain IRB amendment approval,

Objective 2 –

- ✓ Recruit participants

Objective 3 –

Ongoing- Intervention, outcomes, data entry, locking baseline data, submit papers on baseline data

Objective 4–

Ongoing- Data cleaning, locking, analyses

Objective 5-

- ☐ Write and submit intervention papers

Comments/Challenges/Issues/Concerns

- We have closed enrollment and ceased all recruitment efforts. All intervention and outcome events will conclude by December, 2018. Due to the initial slow recruitment, we have moved the primary outcome of the study to a one year change in weight instead of two.
- Projected Expenditure to-date: \$2,593,537.75
- Actual Expenditure to-date: \$2,099,545.69

Updated: 15-April-2018